ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

Certificate Registration No.: **12 100 24126 TMS** / Order No.: **70083720**

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

FRESENIUS KABI

Fresenius Kabi AG

Else-Kröner-Str. 1
61352 Bad Homburg
Germany

for the scope

Design, Development, Production, Storage and Distribution as well as Sales and Marketing of Medicinal Product, Medical Devices, Enteral Nutrition, Active Pharmaceutical Ingredients, Patient-specific Solutions of Pharmaceuticals, and other Healthcare Products, and Services including Technical Service

including the sites see enclosure

has established and applies a Quality Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2025-04-23** until **2028-04-22**.

Fred Wenke
Head of Certification Body
Munich, 2025-03-26

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

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certificate holder:

Fresenius Kabi AG
Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

at the sites	scope
Region Europe	
Fresenius Kabi AG Else-Kröner-Str. 1 61352 Bad Homburg Germany	Global Quality Management, Global Regulatory, Medical & Scientific Affairs, Global IT, Global Procurement, Global Management of and Support for the Operating Units, the Design and Development Centers, the Marketing, Sales, Distribution and Servicing Sites
Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg Germany	Sales and Marketing of Pharmaceuticals, Products for Enteral Nutrition and Medical Devices. Management of Patient Transfer in the Nonclinical Area
Fresenius Kabi Deutschland GmbH Daimlerstr. 22 61352 Bad Homburg Germany	Development, Coordination of Third Party Manufacturing (External Production) and Release of Enteral Nutrition
Fresenius Kabi Deutschland GmbH Pfingstweide 53 61169 Friedberg (Hessen) Germany	Coordination of Third Party Manufacturing (External Production) and Release of Medicinal Products
Fresenius Kabi Deutschland GmbH Gartenstr. 9 99831 Amt Creuzburg/ OT Mihla Germany	Production of Components for Medical Devices and Primary Packaging
Fresenius Kabi Deutschland GmbH **Werk Bad Hersfeld** Robert-Koch-Str. 5 36251 Bad Hersfeld Germany	Design and Development, Product Release and Sales of Non-active Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products
Fresenius Kabi Deutschland GmbH Freseniusstr. 1 61169 Friedberg Germany	Development and Production of Liquid Pharmaceuticals, Active Pharmaceutical Ingredients, Parenteral Nutrition and Medical Devices

Fred Wenke
Head of Certification Body
Munich, 2025-03-26

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at the sites	scope
Region Europe	
Fresenius Kabi Deutschland GmbH Gruener Weg 10 61169 Friedberg Germany	Design and Development of Active Medical Devices for Autotransfusion System, Apheresis and Blood Processing Systems including Devices and Software; Design and Development of Non-active Medical Devices for Blood Processing including Apheresis and Autotransfusion, In-vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Component, including Near Patients Devices
Fresenius Kabi Deutschland GmbH Marienbader Platz 1 61348 Bad Homburg Germany	Design, Development, Production, Distribution and Servicing of Compounding Devices
Fresenius Kabi Logistik GmbH Freseniusstr. 1 61169 Friedberg (Hessen) Germany	Storage and Distribution of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius HemoCare GmbH Gruener Weg 10 61169 Friedberg Germany	Production, Service and Distribution of Active Medical Devices for Autotransfusion System, Apheresis and Blood Processing Systems including Devices and Software; In-vitro Diagnostic Medical Devices (IVD) for Analyzing of Blood Component, including Near Patients Devices
Fresenius Kabi MedTech Services GmbH Am Neuen Berg 8 63755 Alzenau Germany	Service of Medical Devices and Service Training
Fresenius Kabi Austria GmbH Hafnerstr. 36 8055 Graz Austria	Development and Production of Liquid and Lyophilized Pharmaceuticals including Biologicals, Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Food Supplements and Technical Service

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at the sites	scope
Region Europe	
Fresenius Kabi Austria GmbH Estermannstr. 17 4020 Linz Austria	Production, Storage and Distribution, Sales and Marketing of Liquid Pharmaceuticals and Active Pharmaceutical Ingredients
Fresenius Kabi Italia S.r.l. Via Camagre, 41 37063 Isola della Scala-Verona Italy	Production of Liquid Pharmaceuticals, Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, In-vitro Diagnostics, Food Supplements, Laboratory Devices and Cosmetics and Technical Service
Fresenius HemoCare Italia S.r.l. Via San Pietro 1 41037 Mirandola (MO) Italy	Development and Production of Non-active Medical Devices
Fresenius Kabi iPSUM S.r.l. Via E. Mattei, 26 50039 Vicchio, (FI) Italy	Production of Active Pharmaceutical Ingredients and Food Ingredients
Fresenius Kabi iPSUM S.r.l. Via San Leonardo 23 45010 Villadose (RO) Italy	Production, Storage and Distribution of Active Pharmaceutical Ingredients and Bulk Medicinal Products
Fresenius Kabi IPSUM S.r.l. Via Roma 108 20051 Cassina de' Pecchi (MI) Italy	Sales and Marketing of Active Pharmaceutical Ingredients and Bulk Medicinal Product
Fresenius Kabi iPSUM S.r.l. Località Masserie Almieri SNC (Zone Ind.) 86077 Pozzilli (IS) (IS) Italy	Production, Storage and Distribution of Active Pharmaceutical Ingredients and Bulk Medicinal Products
Fresenius Kabi IPSUM S.r.l. Via dello Sviluppo 15 45010 Villadose (RO) Italy	Production as well as Storage and Distribution of Active Pharmaceutical Ingredients

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at the sites	scope
Region Europe	
Fresenius Kabi (Schweiz) AG Am Mattenhof 4 6010 Kriens Switzerland	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices, Homecare Services and Technical Service
Fresenius Kabi SwissBioSim GmbH Terre Bonne Business Park Route de Crassier 23 Bâtiment A3 1262 Eysins Switzerland	Research, Development, Marketing and Sales of Biosimilars
Fresenius Kabi N.V. Brandekensweg 9 2627 Schelle Belgium	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius Kabi AB Islands Brygge 57 2300 København S. Denmark	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius Kabi AB Rapsgatan 7 751 74 Uppsala Sweden	Development, Production and Storage as well as Distribution of Parenteral Solutions as Lipid Emulsions, Clinical Nutrition, Anesthetics, Vitamins
Fresenius Kabi AB Kraftvägen 1 196 37 Kungsängen Sweden	Production, Storage and Distribution of Pharmaceuticals and Active Pharmaceutical Ingredients and Storage and Distribution of Enteral Nutrition
Fresenius Kabi AB Bredgränd 14 753 20 Uppsala Sweden	Sales and Marketing of Medicinal Products and Enteral Nutrition

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at the sites	scope
Region Europe	
Fresenius Kabi Norge AS Innspurten 9 0663 Oslo Norway	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi France S.A.S. 6, Rue du Rempart, 27400 Louviers France	Production of Liquid Pharmaceuticals, Irrigation Solutions and Non-active Medical Devices
Fresenius Vial S.A.S. Le Grand Chemin 38590 Brézins France	Development and Production of Active Medical Devices, Storage and Distribution, Sales, Technical Service and Marketing of Medical Devices
Fresenius Kabi France S.A.S. 5, place du Marivel 92316 Sèvres Cedex France	Sales and Marketing of Medicinal Products, Medical Devices and Enteral Nutrition
Fresenius Kabi France S.A.S. Zone industrielle Ecoparc 2, 350, Allée de la Butte à Colas 27400 Heudebouville France	Storage and Distribution of Medical Devices, Pharmaceuticals and Enteral Nutrition
Fenwal France S.A.S. Etaille 36400 La Chatre France	Production and Distribution of Non-active Medical Devices and Transfusion Accessories, Provision of Sterilization Service for Medical Devices
Fresenius Kabi Ltd. Cestrian Court Eastgate Way Manor Park Runcorn 1+2 Cheshire, WA7 1NT United Kingdom	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service

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at the sites	scope
Region Europe	
Calea UK Ltd Cestrian Court, Eastgate Way, Manor Park, Runcorn Cheshire, WA7 1NT United Kingdom	Production of Patient-specific Solutions of Pharmaceuticals, Sales and Marketing of Enteral Nutrition and Home Care Services
Fresenius Kabi Ltd. **Fresenius Kabi Ireland** Unit 3B Fingal Bay Business Park Balbriggan K32YK12 Dublin CO. Ireland	Storage and Distribution, Sales, Marketing and Home Care relating to Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi AB Ratamestarinkatu 7 a 00520 Helsinki Finland	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius HemoCare Netherlands B.V. **(Enteral Nutrition)** Runde ZZ 41 7881 HM Emmer-Compascuum Netherlands	Production as well as Storage and Distribution of Enteral Nutrition
Fresenius Kabi Nederland B.V. Amersfoortseweg 10e 3712 BC Huis ter Heide Netherlands	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices, Biocides and Technical Service
Fresenius Kabi Polska Sp. z o.o. Sienkiewicza 25 99-300 Kutno Poland	Production as well as Storage and Distribution of Liquid Pharmaceuticals
Clinico Medical Sp. z o.o. ul. Roberta Kocha 1, Blonie 55-330 Miękinia Poland	Production including Sterilization and Distribution of Non-Active Medical Devices for Enteral Feeding, Infusion, Transfusion and Implantable Port Products. The provision of Sterilization Service for Medical Device

Fred Wenke
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Munich, 2025-03-26

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at the sites	scope
Region Europe	
Fresenius Kabi Polska Sp. z o.o. Al. Jerozolimskie 134 02-305 Warszawa Poland	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Labesfal - Laboratorios Almiro S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros Portugal	Production, Storage and Distribution, Sales and Marketing of Medicinal Products including Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals and Medical Devices (Irrigation Solutions)
Fresenius Kabi Pharma Portugal Lda. Taguspark - Edifício Inovação I, 223/224, Av. Jacques Delors 3 2740-122 Porto Salvo Portugal	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Romania S.R.L. Strada Henri Coandă, Nr. 2, Oraş Ghimbav 507075 Judeţ Braşov Romania	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi Hungary Kft. 1025 Budapest Szépvölgyi ut 6. III. Em. Hungary	Storage, Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Food supplements and Medical Devices and Technical Service
Fresenius Kabi s.r.o. Na Strži, 1702/65, Nusle 140 00 Praha 4 Czech Republic	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service in the Czech Republic and Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices in the Slovak Republic
Fresenius Kabi Horatev CZ s.r.o. Horátev 104 289 13 Horátev Czech Republic	Production of Non-active Medical Devices

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at the sites	scope
Region Europe	
Fresenius Kabi España, S.A.U. Dr. Ferran 12 08339 Vilassar de Dalt Spain	Production as well as Storage and Distribution of Liquid Pharmaceuticals and Irrigation Solutions
Fresenius Kabi España, S.A. C/Marina Torre Mapfre - Vila Olimpica 16-18 08005 Barcelona Spain	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius Kabi d.o.o. Radnička cesta 37A 10000 Zagreb Croatia	Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Baltics UAB J. Basanaviciaus Str. 26 03224 Vilnius Republic of Lithuania	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Region Africa	
Fresenius Kabi Manufacturing SA (Pty) Ltd. 6 Gibaud Road, Korsten 6020 Port Elizabeth Republic of South Africa	Production of Liquid Pharmaceuticals
Fresenius Kabi South Africa (Pty) Ltd. Stand 7, Growthpoint Business Park, 162 Tonetti Street 1685 Midrand, Gauteng Republic of South Africa	Production of Patient-specific Solutions of Pharmaceuticals, Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices

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at the sites	scope
Region North Africa	
Fresenius Kabi Tunisia MC 44 Route de Korba 8014 Bir Drassen, Beni Khalled Tunisia	Production and Distribution of Sterile Enteral Nutrition Sets and Sterile Infusion and Transfusion Administration Sets
Region Asia Pacific	
Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mt Kuring-Gai, NSW 2080 Australia	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices in Australia and New Zealand
Fresenius Kabi Australia Pty Limited Unit 2, 18 Powers Road Seven Hills, NSW 2147 Australia	Technical Service for Medical Devices
Fresenius Kabi (Nanchang) Co., Ltd. Qing Lan Road Nanchang Economic & Technological Development Zone Nanchang, Jiangxi Province, P.R. China Post Code: 330013	Development, Production as well as Storage and Distribution of Non-active and Active Medical Devices
Fresenius Kabi (Guangzhou) Co., Ltd. No.43 Baoying Street Guangzhou Free Trade Zone, P.R. China Post Code: 510730	Production and Distribution of Non-active Medical Devices and Liquid Medicinal Products
Fresenius Kabi (China) Co., Ltd. 17F, GrandyVIC Building, No.16 Taiyanggong Mid Street Chaoyang District, Beijing, P.R. China Post Code: 100028	Sales and Marketing of Medical Devices and Technical Service
Beijing Fresenius Kabi Pharmaceutical Co., Ltd. 17F, GrandyVIC Building, No. 16 Taiyanggong Mid Street Chaoyang District, Beijing, P.R. China Post Code: 100028	Sales and Marketing of Medicinal Products

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at the sites	scope
Region Asia Pacific	
Beijing Fresenius Kabi Pharmaceutical Co., Ltd. No. 57 Huatuo Road Zhongguancun Science Park Daxing Bio-Medicine Park, Daxing District Beijing, P.R. China Post Code: 102600	Manufacturing, Storage and Distribution of Medicinal Products and Storage and Distribution of pre-packaged Food
Fresenius Kabi SSPC No. 16, Beizha Road, Mashan, Binhu District Wuxi, Jiangsu Province, P.R. China Post Code: 214092	Development, Manufacturing and Sales of Medicinal Products, Enteral Nutrition, Food for Special Medical Purpose and Dietary Nutrition and Sales of Medical Devices
Fresenius Kabi Hong Kong Ltd. Room 5001-16, 50/F Sun Hung Kai Centre, 30 Harbour Road Wanchai, Hong Kong, P.R. China	Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service
Fresenius Kabi Asia Pacific Ltd. **(The Representative Office of Fresenius Kabi Asia Pacific Limited in Ho Chi Minh City)** Floor 19, Harbour View Tower, 35 Nguyen Hue Street, District 1 Ho Chi Minh City Vietnam	Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Vietnam JSC Harbour View Tower, Floor 19, 35 Nguyen Hue St., Dist. 1 Ho Chi Minh City Vietnam	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi Vietnam Joint Stock Company Area 8, Nhon Phu Ward Quy Nhon, Binh Dinh Province Vietnam	Production of Liquid Pharmaceuticals

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at the sites	scope
Region Asia Pacific	
PT. Fresenius Kabi Indonesia Menara Bidakara 1, 19th floor, Jl. Jend. Gatot Subroto, Kav.71-73 12870 South Jakarta Indonesia	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi India Private Ltd. Ninth Floor, AP 81, S No 83, North Main Road, Mundhwa, Maharashtra Pune - 411036 India	Storage and Distribution, Sales and Marketing of Medical Devices, Medicinal Products and Enteral Nutrition and Technical Service
Fresenius Kabi India Private Ltd. A-3, MIDC. Ranjangaon Ganpati, Tal.-Shirur Dist. Pune - 412220 India	Manufacture, Testing and Supply of Large Volume Parenterals (LVPs) Belonging to Pharmaceutical Formulations
Fresenius Kabi Oncology Limited D-35, Industrial Area Kalyani, Dist. Nadia, West Bengal - 741235 India	Production, Storage and Distribution of Active Pharmaceutical Ingredients
Fresenius Kabi Oncology Limited Village:- Kishanpura, Tehsil:- Baddi Dist.: - Solan, (H.P.) - 173205 India	Technology Transfer, Storage and Distribution and Manufacture of Liquid and Solid Pharmaceuticals
Fresenius Kabi Oncology Limited (Formulation) Echelon Institutional Area, Plot No. 11, Sector - 32 Gurgaon, Haryana - 122001 India	Development and Technology Transfer of Liquid and Solid Pharmaceuticals
Fresenius Kabi Oncology Limited (Development of APIs) Echelon Institutional Area, Plot No. 11, Sector - 32 Gurgaon, Haryana - 122001 India	Development and Technology Transfer of Active Pharmaceutical Ingredients
Fresenius Kabi Japan K.K. 3-32-42, Higashishinagawa Shinagawa-ku, Tokyo 140-0002 Japan	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Laboratory Devices and Technical Services

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at the sites	scope
Region Asia Pacific	
Fresenius Kabi Korea Ltd. 8F-9F Apple Tower 69, Baekjegobun-ro Songpa-gu, Seoul Post Code: 05556 Republic of Korea	Sales and Marketing of Medicinal Products, Medical Devices and Technical Services
Fresenius Kabi Malaysia Sdn Bhd. # 3-1 & 3-2, Axis Technology Centre, Lot 13, Jalan 51A/225 46100 Petaling Jaya, Selangor Malaysia	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi Philippines Inc. Unit A, 18th Floor, Aeon Center, North Bridgeway Avenue Cor. Alabang-Zapote Road 1781 Alabang, Muntinlupa City Republic of the Philippines	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Services
Fresenius Kabi (Singapore) Pte Ltd. 238A Thomson Road #24-03/05 Novena Square Tower A 307684 Singapore Republic of Singapore	Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi (Thailand) Ltd. 93/1 GPF Witthayu Tower B, 10th Floor, Room no.1001-1003, Wireless Road Lumpini, Pathumwan, Bangkok, 10330 Thailand	Sales and Marketing of Medicinal Products, Medical Devices and Enteral Nutrition and Technical Service
Fresenius Kabi Taiwan Ltd. 5F, No. 32, Section 3, Ren-Ai. Rd. Taipei, Taiwan Post Code: 10653	Sales and Marketing of Medicinal Products, Medical Devices, Enteral Nutrition and Technical Services
Region Latin America	
Fresenius Kabi S.A. 2677 Cabildo Av. 10° Floor C1428AAU Buenos Aires Argentina	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service

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at the sites	scope
Region Latin America	
Nutri Home S.A. 2677 Cabildo Av. 10° Floor C1428AAU Buenos Aires Argentina	Sales of Home Care Services
Fresenius Kabi S.A. Del Comercio Boulevard 757 Cordoba Argentina	Production of Patient-specific Solutions of Pharmaceuticals
Fresenius Kabi S.A. Puente del Inca 2450 Calle 9, Lote 155 B1812IDX Carlos Spegazzini - Ezeiza, Buenos Aires Argentina	Production of Patient-specific Solutions of Pharmaceuticals
Fresenius HemoCare Brasil Ltda. Avenida Marginal Projetada 1652 G1 A G8 06460-200 Fazenda Tamboré, Barueri - SP Brazil	Storage and Distribution, Sales and Marketing of Medical Devices and In-vitro Diagnostics
Fresenius Kabi Brasil Ltda. Avenida Marginal Projetada 1652 G1 A G8 06460-200 Fazenda Tamboré Barueri - SP Brazil	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices
FRESENIUS KABI BRASIL LTDA. Rodovia CE 040, Km 10, S/N 61700-000 Jacundá - Aquiraz-Ceará Brazil	Production of Liquid Medicinal Products and Storage and Distribution of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi - PU Anápolis Av. Brasil Norte 1255, Bairro Cidade Jardim 75080-240 Anapolis - GO Brazil	Production of sterile Medicinal Products
Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales 128 06855-690 Itapecerica da Serra - SP Brazil	Production and Distribution of Non-active Medical Devices and In-vitro Diagnostics and Technical Service

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Head of Certification Body
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at the sites	scope
Region Latin America	
Fresenius Kabi S.A. Km 4 1/2 vá Durán tambo Av semillas 090701 Durán Ecuador	Storage, Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition, Medical Devices and Technical Service, Nutrition Center
Fresenius Kabi Chile Ltda. Pintor Cicarelli 235 San Joaquín 8940577 Santiago Chile	Storage and Distribution, Sales and Marketing of Medicinal Products, Medical Devices and Technical Service
Recetario Magistral Endovenoso S.A. Ignacio Valdivieso 2361 San Joaquín 8940577 Santiago Chile	Production, Storage and Distribution and Sales of Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals
Recetario Magistral Endovenoso S.A. Calle 2, N° 1946 Parque Ejercito IX Región Chile	Production, Storage and Distribution and Sales of Patient-specific Compounding Products for Parenteral Nutrition and Pharmaceuticals
Fresenius Kabi Mexico S.A. de C.V. Paseo del Norte 5300-A 45010 Guadalajara Technology Park, Zapopan, Jalisco Mexico	Production, Storage and Distribution of IV-Pharmaceuticals and Enteral Nutrition, Storage, Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi Latin America Exports S.A. Ruta 8 km 17,500 – Edificio @2 Local112 91600 Zonamerica, Montevideo Uruguay	Sales of Medicinal Products, Enteral Nutrition and Medical Devices
Fresenius Kabi Colombia S.A.S. Av. Cra 7 #155C-20 North Point Torre E, Piso 40 Bogotá D.C. Colombia	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service
Fresenius Kabi Perú S.A. Av. Nicolas Arriola 345-349 Urb Santa Catalina - La Victoria Lima 13 Peru	Storage and Distribution, Sales and Marketing of Medicinal Products, Enteral Nutrition and Medical Devices and Technical Service

Fred Wenke
Head of Certification Body
Munich, 2025-03-26

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

ENCLOSURE OF CERTIFICATE

Certificate Registration No.: **12 100 24126 TMS** / Order No.: **70083720**

certificate holder:

Fresenius Kabi AG
Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

at the sites	scope
Region North America	
Calea Ltd. 7111A-6th Street S.E: Calgary, Alberta T2H 2M8 Canada	Compounding of Patient-specific Solutions of Pharmaceuticals and Storage and Distribution
Calea Ltd. 2785 Skymark Avenue, Unit 2 Mississauga, Ontario L4W 4Y3 Canada	Compounding of Patient-specific Solutions of Pharmaceuticals, Storage and Distribution
Calea Vancouver Inc. Unit 130-8061 Lougheed Hwy. Burnaby, BC V5A 1W9 Canada	Compounding of Patient-specific Solutions of Pharmaceuticals and Storage and Distribution
Fresenius Kabi Canada Ltd. 165 Galaxy Blvd, Suite 100 Toronto, Ontario M9W 0C8 Canada	Sales and Marketing of Medicinal Products and Medical Devices and Technical Service
Calea Pharmacy Ltd. 41 Brockley Drive, Unit 12 Stoney Creek, Ontario L8E 3P1 Canada	Compounding of Patient-specific Solutions of Pharmaceuticals and Storage and Distribution
Fresenius Kabi Canada Ltd. 2400 Skymark Avenue, Unit 4 Mississauga L4W 5K5 Canada	Production, Storage and Distribution and Sales of Compounded Products and Pharmaceuticals

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at the sites	scope
Region North America	
Fresenius Kabi USA, LLC 2020 North Ruby Street Melrose Park, IL 60160 USA	Production and Storage of Liquid and Lyophilized Pharmaceuticals
Fresenius Kabi USA, LLC 3159 Staley Road Grand Island, NY 14072 USA	Production and Storage of Liquid and Lyophilized Pharmaceuticals
Fresenius Kabi USA, LLC 2045 North Cornell Avenue Melrose Park, IL 60160 USA	Development and Testing of Liquid and Lyophilized Pharmaceuticals and Combination Products
Fresenius Kabi USA, LLC 5200 Corporate Parkway West Wilson, NC 27893 USA	Production, Storage and Distribution of Liquid Aseptically Filled and Terminally Sterilized Pharmaceutical Products and Combination Products
Fresenius Kabi LLC 402 Apple Valley Road Duncan, SC 29334 USA	Storage and Distribution of Medicinal Products, Enteral Nutrition, Combination Products, Medical Devices and Spare Parts
Fresenius Kabi LLC 5245 North Sloan Lane Suite 100 North Las Vegas, NV 89115 USA	Storage and Distribution of Medicinal Products, Enteral Nutrition, Combination Products, Medical Devices and Spare Parts
Fresenius Kabi LLC 11900 122nd Street Pleasant Prairie, WI 53158 USA	Storage and Distribution of Medicinal Products, Enteral Nutrition, Combination Products, Medical Devices and Spare Parts

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Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

at the sites	scope
Region North America	
Fresenius Kabi Warrendale 770 Commonwealth Drive Warrendale, PA 15086 USA	The Manufacture of Active and Non-Active Medical Devices for Infusion, Apheresis, Autotransfusion, Plasmapheresis, Blood Collection and Cell Processing Equipment and Accessories including Software, Servicing of Infusion Pump Devices
Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, IL 60047 USA	Sales and Marketing of Medicinal Products and other Health Care Products
Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047 USA	Design, Development and Distribution of Disposables, Solutions, Systems and Accessories for the Collection, Processing and Storage of Blood and Blood Components to include the Installation and, Service of Medical Device Systems
Fenwal International, Inc. Carretera Sánchez Km, 18,5 Parque Industrial Itabo, Zone Franca Ind. de S.C. 91000 Haina Dominican Republic	Production including Sterilization and Distribution of Non-active Medical Devices for Infusion, Transfusion, Blood processing, Blood sampling, Blood Donation and Filtration. The Provision of Sterilization Service for Medical Devices
Fenwal Inc. Road 122 km. 05 00683 San German Puerto Rico	Production including Sterilization and Distribution of Non-active Medical Devices for Transfusion, Blood Sampling, Blood Donation and Filtration
Fenwal Inc. Road 357 km. 08 00606 Maricao Puerto Rico	Production including Sterilization and Distribution of Non-active Medical Devices for Blood Sampling, Blood Donation and Filtration

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